

Governor

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Guidance for Health Care Providers and Vaccine Administrators Monkeypox JYNNEOS Vaccination Information

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Summary of Recent Changes

- On 10/27/2022, New York State Executive Order 20.2, which suspended the requirement that
 health care providers who administer monkeypox vaccines to persons 19 years of age or older
 obtain consent of the vaccinees to report such vaccination to New York State Immunization
 Information System (NYSIIS) or the New York City Immunization Registry (CIR), expired. Health
 care providers who administer monkeypox vaccines to persons 19 years of age and older must
 now obtain consent to report such vaccinations to NYSIIS or CIR.
- While New York State Executive Order 20.2 has expired, non-traditional vaccinators such as
 dentists, advanced or intermediate emergency medical technicians, licensed or certified
 professional midwives, registered nurses, licensed practical nurses, optometrists, paramedics,
 pharmacists, pharmacy interns, pharmacy technicians, physician assistants, podiatrists,
 respiratory therapists, and veterinarians may continue to vaccinate according to the Food and
 Drug Administration (FDA) emergency use authorization (EUA) and the Public Readiness and
 Emergency Preparedness (PREP) Act.
- As of October 6, 2022, monkeypox virus has been added to the list of sexually transmitted diseases pursuant to Section 23.1 of Title 10 of the official New York Codes, Rules, and Regulations. This addition was enacted through emergency regulations which are in effect for 90 days (until January 4, 2023) and are subject to potential continuation or permanent adoption. The Public Health Law authorizes health care providers to diagnose, treat, and prescribe care related to sexually transmitted infections (STIs) for minors under the age of 18 without the consent of a parent or guardian. Therefore, parent or guardian consent is no longer required to administer the JYNNEOS vaccine to minors, under the conditions outlined below.
- As a reminder, statewide eligibility has now been expanded to include immunization of all individuals at risk of becoming infected with Monkeypox.
- As of September 28, 2022, the Centers for Disease Control and Prevention (CDC) updated its
 <u>Interim Clinical Considerations for the Use of JYNNEOS</u> with respect to the Intradermal (ID)
 administration of the JYNNEOS vaccine; schedule and dosing regimens for JYNNEOS vaccine for
 those younger than the age of 18; coadministration of JYNNEOS vaccine with tuberculin skin
 test; and vaccination administration considerations for specific populations.

Key Points Regarding Monkeypox Vaccine

- Monkeypox is a disease caused by infection with the monkeypox virus. Monkeypox virus is part
 of the *orthopoxvirus* genus, the same genus of viruses that causes smallpox. Monkeypox
 symptoms are like smallpox symptoms, but milder, and the clade of monkeypox virus circulating
 in the current 2022 outbreak is rarely fatal.
- There are currently two vaccines available to help protect against *orthopoxvirus* infection, including monkeypox and smallpox: JYNNEOS and ACAM2000. New York State currently is <u>not</u> pursuing the deployment or use of the ACAM2000 vaccine. ACAM2000 is a live, attenuated, replication-competent vaccine indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.
- Previous smallpox vaccination probably does provide some protection, but it may not be
 lifelong; therefore, in the setting of the current outbreak, vaccines and other medical measures
 should be provided to eligible people previously vaccinated against smallpox.
- A CDC-held Emergency Access (EA) Investigational New Drug (IND) protocol allows use of ACAM2000 for non-variola *orthopoxvirus* Infection (e.g., monkeypox) during an outbreak.

- Information on how to submit an EA-IND application can be found at <u>IND Applications for</u> Clinical Treatment (Expanded Access): Overview | FDA.
- The CDC recommends that JYNNEOS is used as a preferred option to ACAM2000 for primary orthopoxvirus vaccination and booster doses, in addition to use as pre-exposure prophylaxis against orthopoxvirus infection among persons at risk for such exposures.
- The effectiveness of the JYNNEOS vaccine against the virus circulating in the current 2022
 outbreak is currently unknown. To better understand the protective benefits of this vaccine
 during the current outbreak, data will be collected to help define JYNNEOS vaccine efficacy. The
 immune response takes 14 days after the second dose for maximal development.
- Vaccination against monkeypox remains an important public health strategy for protecting public health.
- New York State's response to the monkeypox outbreak can be found at the NYSDOH website.

JYNNEOS (also known as IMVAMUNE, IMVANEX, MVA) Vaccine Use, Eligibility and Availability

JYNNEOS is a live, attenuated, non-replicating vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating *orthopoxvirus*:

- JYNNEOS, the Modified Vaccinia Ankara (MVA) vaccine, was <u>approved</u> in 2019 for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.
- JYNNEOS is administered via the standard regimen, beneath the skin (subcutaneously) as two 0.5 mL doses, four weeks (28 days) apart.
- The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) on 8/9/2022 for the emergency use of JYNNEOS for active immunization by subcutaneous injection for prevention of monkeypox disease in individuals less than 18 years of age determined to be at high risk for monkeypox virus infection. While there is no lower age bound for the standard dosing (subcutaneous) of JYNNEOS, any provider with questions regarding administration for young children, especially those under 6 months of age, may contact the NYSDOH at immunize@health.ny.gov.
- For individuals 18 years of age and older determined to be at high risk of monkeypox infection, the EUA now allows for -the JYNNEOS vaccine to be administered between the layers of the skin (intradermally) at a volume of 0.1 mL. As with subcutaneous administration, two doses of the vaccine should be given four weeks (28 days) apart.
- The following are the exceptions to the recommended two dose series:
 - O JYNNEOS is only for prevention and not treatment. Persons with symptomatic infection should discuss medical treatments such as TPOXX with their healthcare provider. If someone becomes symptomatic between their first and second JYNNEOS dose, they should not receive the second dose.
 - O In contrast, an immunocompromised person who is diagnosed with monkeypox after their first dose of JYNNEOS may be eligible to receive the second dose on a case-by-case basis, using shared decision making, and clinical judgment of the health care provider. More information can be found within the <u>Vaccination Administration Considerations</u> for <u>Specific Populations</u> at the <u>CDC's Interim Clinical Considerations for the use of</u> JYNNEOS.
 - An individual who has been diagnosed with monkeypox during the current outbreak is not recommended to be vaccinated at this time because monkeypox infection likely confers immune protection.

For intradermal administration training resources, please visit the New York State Department
of Health (NYSDOH) website at Monkeypox for Healthcare Providers (ny.gov). The CDC has also
provided multiple resources regarding intradermal administration.

Currently, CDC is working with states to deploy FDA-approved JYNNEOS vaccine that can be used as preexposure prophylaxis (Prep), standard post-exposure prophylaxis (Pep) for monkeypox, or post-exposure prophylaxis (Pep)++. The NYSDOH is distributing vaccine as it becomes available to states, in accordance with CDC guidance.

NOTE: People with a known exposure to a suspected or confirmed monkeypox case in the past 14 days should work directly with their local health department (LHD) and health care provider to discuss obtaining the JYNNEOS vaccine as quickly as possible.

<u>Statewide eligibility has now been expanded</u> to include all individuals at risk of becoming infected with monkeypox. This includes the following:

- Individuals with recent exposure to a suspected or confirmed monkeypox case within the past 14 days. (PEP)
- Those at high risk of a recent exposure to monkeypox, including gay men and members of the bisexual, transgender, and gender non-conforming community and other communities of men who have sex with men and who have engaged in intimate or skin-to-skin contact with others in the past 14 days in areas where monkeypox is spreading. (PEP++)
- Individuals who have had skin-to-skin contact with someone in a social network experiencing monkeypox activity, including men who have sex with men who meet partners through an online website, digital application ("app"), or social event, such as a bar or party. (PEP++)
- Any individual who may be at risk of <u>future</u> exposure to infection with monkeypox, even though they are not at high risk of a recent exposure to monkeypox. (PrEP)
- Statewide eligibility will be posted and updated at the NYSDOH Monkeypox website.

Special Considerations for Individuals Receiving Orthopoxvirus JYNNEOS Vaccine

- Based on this EUA expansion, there are several updates to the vaccine schedule and dosing regimen for the JYNNEOS vaccine.
- Currently, intradermal (ID) administration is recommended for persons 18 years and older who DO NOT have a history of keloid scars. Intradermal administration is NOT approved for individuals under the age of 18 years of age.
- Persons aged 18 years or older who received one JYNNEOS vaccine dose with the standard subcutaneous regimen may receive a second dose with the alternative intradermal regimen at the recommended interval (i.e., 28 days) to complete the vaccination series. There are exceptions to the two-dose primary series.
- A person whose 18th birthday occurs between their first and second dose may complete the series with the alternative regimen.
- For individuals younger than 18 years old, or people of any age who have a history of developing keloid scars, JYNNEOS should be administered by subcutaneous injection (standard regimen). For further information, please see CDC clinical considerations for children and adolescents.
- CDC recommends that the vaccine be given within 4 days from the date of exposure to prevent onset of the disease. If given between 4–14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease.

- If the second dose is not administered during the recommended interval, it should be administered as soon as possible. There is no need to restart or add doses.
- JYNNEOS can be administered to people with immunocompromising conditions. A <u>summary of vaccination administration considerations</u> for specific populations by age and medical condition can be found within the CDC's Interim Clinical Considerations for Orthopox Vaccines.
- Currently, there is no data on administering JYNNEOS at the same time as other vaccines.
 JYNNEOS typically may be administered without regard to timing of other vaccines. There are additional considerations if administering a COVID-19 vaccine. See Interim Clinical Considerations for Coadministration.
- Currently, there are no data on administering JYNNEOS vaccine at the same time as the tuberculin skin test (TST). If a delay in TST will cause substantial burden, then TST should not be delayed. However, if a delay in TST will **not** cause substantial burden then it a delay of 4 weeks after JYNNEOS vaccination is preferred.
- People with underlying heart disease or three or more major cardiac risk factors should be counseled about the theoretical risk for myopericarditis following vaccination with JYNNEOS, given the uncertain etiology of myopericarditis associated with replication-competent smallpox vaccines such as ACAM2000.
- A person is considered to reach peak immunity 14 days after second dose of JYNNEOS administered 28 days apart.
- Updates to the dosing regimen and vaccination schedule are summarized in <u>Table 2</u> within the CDC's Interim Clinical Considerations for JYNNEOS.

Scheduling the Second Dose of JYNNEOS Vaccine

JYNNEOS vaccine is a two-dose vaccine, administered 28 days apart. Circumstances may arise where individuals need to receive their second dose at a different location than their first. Providers who have determined that the individual cannot return to the location where they received their first dose should either schedule a second dose for these individuals elsewhere or must supply information on how/where to obtain a second dose of vaccine. Please ensure all individuals are informed on how to locate a second dose appointment. Information about counties that have received JYNNEOS vaccine can be found on the NYSDOH monkeypox website.

It is not recommended to give the second dose before the minimum interval of 28 days, but it can be given up to 4 days before and 7 days after the minimum interval of 28 days (24-35 days). If there is a delay beyond 35 days in administering the second dose, give the second dose as soon as possible and do not restart the series.

Vaccine Safety

- Do not vaccinate those with a history of a severe allergic reaction (e.g., anaphylaxis) after a
 previous dose of JYNNEOS. For complete information on contraindications and precautions for
 use of JYNNEOS vaccine, please <u>CDC's JYNNEOS Vaccine Interim Guidance</u>.
- Precautions include a history of severe allergic reaction (e.g., anaphylaxis) to benzonase, gentamicin or ciprofloxacin, history of severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND currently avoiding all chicken and egg products
 - After discussing risks and benefits with the patient, persons with a precaution to vaccination may be vaccinated with a 30-minute observation period or referred for allergist-immunologist consultation prior to vaccination

- Because of the documented, though low risk, for myocarditis after receipt of both ACAM2000 and mRNA COVID-19 vaccines and the unknown risk for myocarditis after JYNNEOS, individuals might consider waiting 4 weeks after *orthopoxvirus* vaccination (either JYNNEOS or ACAM2000) before receiving an mRNA COVID-19 vaccine, particularly adolescent or young adult males. However, if an *orthopoxvirus* vaccine is recommended for prophylaxis in the setting of an outbreak, administration of *orthopoxvirus* vaccine should not be delayed because of recent receipt of an mRNA COVID-19 vaccine. No minimum interval between mRNA COVID-19 vaccination and *orthopoxvirus* vaccination is necessary.
- For vaccines inadvertently administered intramuscularly (IM) please refer to the CDC's recommendations on <u>vaccine administration errors and deviations</u>.
- For vaccines inadvertently administered with improper intradermal technique, please refer to the CDC's recommendations on vaccine administration errors and deviations.
- There is insufficient human data on JYNNEOS in pregnancy. Studies in animals show no evidence
 of harm to the developing fetus. JYNNEOS safety and efficacy has not been evaluated in people
 who are breastfeeding or in young children. The risks and benefits of JYNNEOS should be
 discussed to determine if vaccine can be offered to pregnant or breastfeeding people who are
 otherwise eligible. Please see CDC's guidance for monkeypox in individuals who are pregnant or
 breast feeding.
- You must report any adverse events that occur after vaccination to the Vaccine Adverse Events Reporting System (VAERS) at info@VAERS.org or by calling 1-800-822-7967.
- VSafe will be added for monitoring in the future.

Consent for Vaccination of Minors

On October 6, the Department of Health adopted an emergency regulation adding monkeypox to the list of sexually-transmitted infections (STIs) as included in Section 23.1 of Title 10 of the official New York Codes, Rules, and Regulations. This emergency regulation is in effect for 90 days (until January 4, 2023) and is subject to possible continuation or permanent adoption.

Adolescent minors under the age of 18 are permitted to consent to their own STI-related care, now including monkeypox-related care and vaccination.

6 month-12-year-olds:

For minors who are 6 months through 12 years of age, under PHL §2504(5), a minor's parent, legally appointed guardian, custodian (i.e., one who has assumed the charge and care of the minor because the minor's parents or legal guardian have died, are imprisoned, are mentally ill, have been committed to an institution, have abandoned or deserted the minor, or are living outside of the state or because the minor's parents or legal guardian's whereabouts are unknown), and a grandparent, an adult sibling, an adult aunt or uncle, any of whom has assumed care of the minor, and an adult who has care of the minor and has written authorization to consent from the minor's parent, legally appointed guardian, or custodian, may give effective consent. However, family members listed above who have assumed care of the minor or adults with written authorization to consent to immunization may not consent if they have reason to believe that the minor's parent, legal guardian or custodian objects to the immunization. Any provider with questions regarding administration for young children may contact the NYSDOH at immunize@health.ny.gov.

13-17-year-olds:

For minors 13-17 years of age, consent can be obtained the same as for minors under 13 (see above).

In addition, sexually active minors with medical decision-making capacity may consent on their own without the consent or knowledge of another person. The term "sexually active" can be interpreted in different ways. Providers may consider anyone who is at-risk of STI as being sexually active. This could include people who may not consider themselves sexually active per se, such as people who: engage in sexual behaviors whether or not intercourse is involved, anticipate sexual initiation, have had sex in the past but do not have a current partner, are unable or uncomfortable disclosing their sexual activity to their provider(s), and others. For clinical purposes, "sexually active" can be broadly interpreted to include people who report being sexually active currently, previously, or anticipate becoming so in the future.

Vaccine Reporting

Health care providers who administer monkeypox vaccines to persons younger than 19 years of age are required to report such vaccinations to the New York State Immunization Information System (NYSIIS) or to the New York City Immunization Registry (CIR).

Health care providers who administer monkeypox vaccines to persons 19 years of age and older must obtain patient consent to report such vaccinations to the New York State Immunization Information System (NYSIIS) or to the New York City Immunization Registry (CIR).

Questions and issues regarding vaccine reporting to NYSIIS should be directed to nysiis@health.ny.gov.

Administration of JYNNEOS Vaccine

Prior to JYNNEOS vaccine administration

Inform each patient of the risks, benefits, and alternatives of receiving the JYNNEOS vaccine. As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the Vaccine Information Statement prior to the individual receiving vaccine.

Provide each patient a copy of the JYNNEOS Vaccine Information Statement (VIS) or direct the individual to the website https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf) and VIS in Spanish here. When administrating JYNNEOS subcutaneously to individuals under the age of 18, the individual should receive the EUA fact sheet (https://www.fda.gov/media/160773/download), also available in Spanish

JYNNEOS Vaccine Administration

- Yellow capped single-dose vial with turquoise and white label.
- Can be administered as a subcutaneous (Subcut) injection or intradermal (ID) injection. Allow the vaccine to thaw and reach room temperature before use. A frozen vial will take less than 10 minutes to thaw at room temperature.
- ACIP recommendations on the administration of the JYNNEOS vaccine can be found here.
- Information regarding vaccine administration errors and deviations can be found here.
- Contact information for manufacturer email: medical.information US@bavarian-nordic.com
 U.S. phone number: 1-844-422-8274; U.S. fax number: 1-843-422-8274

Subcutaneous Administration (Standard Regimen)

 Allow JYNNEOS vaccine to thaw and reach room temperature before use and should be a milky, light yellow to pale white colored suspension.

- Swirl the vial gently for at least 30 seconds.
- Withdraw full dose of **0.5 mL** using a 23–25 gauge, 5/8" needle into a sterile syringe for injection.
- For persons >12 months of age: administer JYNNEOS subcutaneously by pinching up fatty tissue over the triceps area in the upper arm and insert the needle at a 45-degree angle.
- For infants <12 months of age: administer JYNNEOS subcutaneously by pinching up fatty tissue over the anterolateral thigh and insert the needle at a 45-degree angle.
- Preparation and administration of the standard dosing regimen:
 <u>https://www.cdc.gov/poxvirus/monkeypox/files/interim-considerations/guidance-Jynneos-prep-admin-stand.pdf.</u>

Intradermal (ID) Administration (Alternate Regimen)

- Allow JYNNEOS vaccine to thaw and reach room temperature before use, and should be milky, light yellow to pale white colored suspension.
- Swirl the vial gently for at least 30 seconds.
- Withdraw full dose of **0.1 mL** using 26 or 27 gauge, 1/4, 3/8, or /1/2" needle with a short bevel into a tuberculin syringe.
 - The use of "no" or "low" dead space needles/syringes will ensure the most accurate measurement of 0.1 mL and maximize the number of doses able to be drawn from the vial.
 - o If a full 5th dose cannot be drawn from the vial (e.g., less than 0.1 mL) DO NOT combine vaccine from multiple vials to create a full dose. Infection control and safe injection practices should always be followed.
- Select and cleanse vaccination site 2-4 inches below the antecubital fossa (elbow) on the volar (inner) surface of the forearm
 - The preferred location for <u>intradermal administration</u> is the forearm. However, alternate sites based on patient preference including the upper back under shoulder blade (scapula), deltoid, and upper chest could be considered.
- While pulling the skin taut, position the needle bevel facing up and insert the needle at a 5-to 15-degree angle into the dermis.
- Slowly inject 0.1mL intradermally producing a noticeable pale elevation of the skin (wheal or bleb). A wheal or bleb is desirable but not required to count as a valid dose.
- A bandage may be placed over the injection site as needed.
- A person who presents for their second JYNNEOS vaccine dose who is still experiencing
 erythema or induration at the site of intradermal administration of the first vaccine dose (e.g.,
 the forearm) may have the second dose administered intradermally in the contralateral forearm
 or if that is not an option, in the upper back below the scapula, or at the deltoid.
- Resources to assist in intradermal (ID) administration have been provided by the CDC in <u>video</u> and photograph formats.
- The CDC has provided resources regarding preparation and administration of the alternative dosing regimen here.
- Interim recommendations for vaccine administration errors and deviations for Intradermal administration can be found at the CDC's Clinical Considerations for JYNNEOS.

Post Vaccine Waiting Time

• Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:

- 30 minutes: individuals with a history of anaphylaxis to gentamicin, ciprofloxacin, chicken, or egg protein (AND who are currently avoiding exposure to all chicken or egg products).
- 15 minutes: for all other individuals.

Vaccine Management

All providers must adhere to all requirements outlined in the HHS Monkeypox Vaccination Program
Provider Agreement. Providers located outside NYC must sign and return a NYSDOH Outbreak Vaccine Provider Agreement for JYNNEOS vaccine.

Ordering Instructions

- Monkeypox vaccines are currently only available through the Strategic National Stockpile (SNS).
- Requests for vaccine from the SNS will be made by NYSDOH or NYCDOHMH according to CDC defined allocation and distribution protocols.
- NYSDOH will provide vaccine through local health departments (LHDs) and their health care provider network and county partners.

General Storage and Handling Requirements

Vaccines must be stored and handled properly from the time they are manufactured until they are administered to maintain the cold chain, thus protecting the potency and effectiveness of the vaccine, and ensuring vaccine recipients are fully and safely protected from vaccine-preventable diseases. Detailed information regarding vaccine storage and handling requirements is available at CDC Vaccine Storage and Handling Toolkit. Additional details on JYNNEOS storage, transport, and temperature monitoring requirements can be found in Appendix A of this document. Storage and handling summary specific to JYNNEOS can be accessed here.

JYNNEOS Storage and Handling Requirements

- <u>Package insert</u> (https://www.fda.gov/media/131078/download). Please note that the JYNNEOS manufacturer has provided a https://expr.hhs.gov/SNS/Documents/MVA-BN-Information-Ltr-Effective-14June2022.pdf.
- The vaccine comes in packages of 20 vials.
- Keep frozen at -25°C to -15°C (-13°F to +5°F) until expiration date.
- DO NOT store on dry ice or below -50°C (-58°F).
- Store in the original package to protect from light.
- Do not refreeze a vial once it has been thawed.
- Once thawed unpunctured vials may be kept refrigerated at +2°C to +8°C (+36°F to +46°F) for 8 weeks.
 - Count 8 weeks from when the vial was first thawed and mark this "beyond use" date on the vial label. If the product expiration date on the carton is earlier, write that on the vial instead.
- Unpunctured vials may be stored at room temperature between 8°C and 25°C (46°F and 77°F) for up to 6 cumulative hours.
- After first puncture, vials can be stored at +2°C to +8°C (+36°F to +46°F) for up to 8 hours. Discard any remaining vaccine after 8 hours.
- NEVER store vaccine in a "dormitory style" storage unit.

Vaccine Expiration Dates

Determining when a vaccine expires is a critical step in proper storage and handling. The expiration date should always be checked prior to preparing or administering vaccine. Expired vaccine should NEVER be administered. As additional stability data become available, the expiration dates for some products may change.

Expiration date is printed on the vaccine carton, not individual vials. The expiration date can also be looked up at Monkeypox (hhs.gov).

Temperature Monitoring Requirements

- You must use a digital data logger (DDL) to always monitor the temperature of vaccines during storage and transport.
- Record temperatures daily on a temperature log. Examples can be found at https://www.immunize.org/handouts/temperature-logs.asp.
- When positioning a DDL in a permanent vaccine storage unit, place the buffered probe in the center of the unit with the vaccines surrounding it, and attach the temperature display to the outside of the unit.
- When packing a DDL in a vaccine transport container:
 - Make sure the buffered probe has been conditioned in the refrigerator or freezer for at least 5 hours prior to transport.
 - o Remember to reset the minimum/maximum temperature display.
 - Place buffered probe as close as possible to vaccines in the transport container.
 - o Do not place buffered probe directly next to ice packs or other coolants.
 - Attach temperature display to the outer lid of the transport container whenever possible.
- Temperature excursions must be reported to the manufacturer to determine vaccine viability. DO NOT use vaccine that has experienced a temperature excursion until viability has been determined. Contact Bavarian Nordic at toll-free phone 1-800-675-9596. General questions on temperature excursions can be sent to vaccinetempexcursion@health.ny.gov.

Inventory Management

- Doses, lot, and expiration information must be manually entered as <u>inventory in NYSIIS</u> or CIR (<u>https://www1.nyc.gov/assets/doh/downloads/pdf/cir/covid-19-transfer-vim-guide.pdf</u>) upon receipt. This must be done manually since orders are not managed in these systems.
- Effective August 29, 2022, providers should count inventory as each vial of vaccine equal to 5 doses (i.e., receipt of 100 vials would be entered as 500 doses in NYSIIS/CIR).
- Doses administered to persons 19 years of age and older who provide consent to having their immunizations reported to NYSIIS/CIR must choose the eligibility category of '317' to have doses administered to patients automatically deduct from inventory in NYSIIS/CIR.
- If a patient age 19 or older does not consent to having their immunization reported to NYSIIS, inventory must be manually updated. Please see Appendix A for instructions.
- Providers must track any vaccine doses that are unused, spoiled, damaged, or expired as wastage in the IIS.
- Inventory must be verified in NYSIIS/CIR by COB each Monday. Count each vial as 5 doses for NYSIIS inventory.

Vaccine Redistribution

- Vaccine should not be redistributed outside of the county without NYSDOH approval or outside of NYC without NYCDOHMH approval.
- When redistributing vaccine to other providers, the <u>New York State Vaccine Program Storage</u> and <u>Transport Guidance for Jynneos Vaccine</u> must be followed. Ensure continued temperature monitoring via digital data loggers.
 - Complete the appropriate transport tracking sheet, including temperatures during transport, found in this guidance and maintain for your records.
- The releasing provider must track date and time of redistribution, receiving provider info, lot number, expiration date, and number of doses redistributed.
- Receiving and sending providers are required to update their active inventory in NYSIIS or CIR for improved tracking.

Resources for JYNNEOS

- CDC Interim Clinical Considerations for JYNNEOS
- JYNNEOS Emergency Use Authorization for caregivers
- JYNNEOS Emergency Use Authorization for HCP
- CDC's Vaccine Administration Resource Library
- Subcutaneous Injection Administration Video
- JYNNEOS Subcutaneous Vaccine Preparation and Administration Summary: see Related Resources
- CDC's General Best Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions
- Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting
- JYNNEOS Vaccine Package Insert
- MMWR for JYNNEOS
- CDC's General Best Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions
- CDC COCA Call
- Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting
- BLA Clinical Review Memorandum
- FDA Statement on JYNNEOS

APPENDIX A

New York State Immunization Information System (NYSIIS)

Updating Inventory – Decrementing doses administered to adults who do not consent to share immunization information with NYSIIS

To keep NYSIIS inventory accurate and account for doses administered to adults age 19 and older who do not consent to have their immunizations report to NYSIIS, inventory must be manually modified to subtract those doses from inventory.

To change information on existing vaccine lots, follow these steps:

- 1. Click on Manage Inventory under the Inventory section of the menu panel.
- 2. Press Show Inventory
- 3. The inventory table shown by default will include active vaccine lots within the organization.
- 4. Select the vaccine lot you wish to update by clicking on the vaccine's trade name hyperlink, which is underlined and in blue.
- 5. To modify the quantity of doses on hand, enter the following information:
 - Under "Action" choose "Subtract" from the inventory on hand.
 - Under "Amount" enter the quantity of inventory to be subtracted. This should be the number of adults age 19 and older who did not consent to having their immunization reported to NYSIIS.
 - Choose "Adults not in NYSIIS" from the 'Reason' drop down list.

